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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/370,860	08/09/1999	JAGATH L. KADURUGAMUWA	7933.36US01	8609

7590 12/21/2001

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EXAMINER

ZEMAN, ROBERT

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/21/2001

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/370,860

Applicant(s)

KADURUGAMUWA ET AL.

Examiner

Robert A Zeman

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-22 is/are pending in the application.
- 4a) Of the above claim(s) 7-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6 and 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-3 and 5-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Continued Prosecution Application

The request filed on 9-20-2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/370,860 is acceptable and a CPA has been established. An action on the CPA follows.

The amendment filed on 9-20-2001 has been added. Claims 1 and 6 have been amended. Claim 4 has been canceled. Claims 18-22 have been added.

Election/Restrictions

This application contains claims 7-17 drawn to an invention nonelected with traverse in Paper No. 7.

Claim Rejections Withdrawn

The rejection of claims 1 and 6 under 35 U.S.C. 112, second paragraph, for being vague and indefinite by using the phrase "carrier strain" is withdrawn in light of the amendment thereto.

The rejection of claims 1-6 under 35 U.S.C. 103(a) as being unpatentable over Hamstra et al. (WO 92/05194, IDS-6) in view of Viret et al. (EP 564 689, IDS-6) and Van Der Ley et al. (WO 94/08021, IDS-6) is withdrawn in light of the amendment thereto. The aforementioned claims have been amended to read on cellular vaccines.

Art Unit: 1645

Claim Rejections Maintained

The rejection of claim 6 under 35 U.S.C. 112, second paragraph, for being vague and indefinite by using the phrase "against another infectious agent" is maintained for reasons of record. Applicant has failed to address this rejection.

New Grounds of Rejection

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-6 and 18-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The aforementioned claims are drawn to cellular vaccines against an infectious disease caused by an infectious agent and a method of making said vaccines. For a composition to be considered a vaccine, said composition must provide protective immunity, demonstrable by viral challenge experiments, in a reasonable model system. The specification, as filed, does not set forth that the claimed compositions provide any sort of protective immunity in any model system that can be extrapolated to humans or higher mammals. Applicant describes the "immunization" of groups of BALB/c mice with one of 6 test vaccines (Ty21a, PAO1 MVs, M90T MVs, Ty21a + M90T MVs, Ty21a + PAO1 MVs and Ty21a + M90T MVs + PAO1 MVs. Said mice were then bled and the resulting sera was tested for MVs-specific antibodies

Art Unit: 1645

(antibodies directed to LPS or OMPs). The "inoculated" mice were never challenged with an "infectious agent" to determine whether the test vaccines provided protective immunity against said agent. One cannot correlate the production of antibodies with the induction of protective immunity. For example, people infected with HIV-1 produce antibodies to said virus but said antibodies do not confer a "protection" to the infected individual. While the skill in the art in immunology, bacteriology and virology is high, to date, prediction of protective immunity for any given composition is quite unpredictable. Given the lack of success in the art, the lack of working examples, and the unpredictability of the generation of protective immunity, the specification, as filed, is not enabling for any type of vaccine.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-6, and 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the use of the phrase "comprising a bacterial carrier". It is unclear whether said phrase is describing the cellular vaccine or the infectious agent. As such, it is impossible to determine the metes and bounds of the claimed invention.

Claims 1 and 6 are rendered vague and indefinite by the use of the phrase "an amount of antigen". What amount? As written, it is impossible to determine the metes and bounds of the claimed invention.

Art Unit: 1645

Claim 1 is rendered vague and indefinite by the use of the phrase "associated with its surface". How is the antigen "associated"? Is integrated into the cell wall or merely adhered to its exterior portion? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 21 is rendered vague and indefinite by the inconsistent use. In the preamble of the claim, Applicant refers to "a cell wall" then subsequently refers to "the cell wall". The article "a" suggests that there is more than one possible cell wall. The article "the" refers to a singular object. Consequently, it is impossible to determine the limitations of the claimed invention.

Conclusion

No claim is allowed.

Claims 1-3, 5-6 and 18-22 are free of the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on M-Th 7:30 am - 5:00 pm and Alternate Fridays.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donna Wortman can be reached on (703) 308-1032. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Application/Control Number: 09/370,860

Page 6

Art Unit: 1645

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman
December 18, 2001